CEEK

by user-facilities, butors and manufacturers ATORY reporting

	One Civic Transment on texal?
Wfr Report#	
JF/Importer Report 8	

Form Approved, OMB No. 0910-0291, Expires: 6/30/2015

FORM FDA 350)A:
	04 (2113)				Page
A. PATIENT IN					
1. Patient Identifier b) (6)	2. Age et Time of Event:	52	Years	3. Sex	4. Weight
	or	/1- \	(O)	Female	or Ibi
in confidence	Of Birth:	(D)) (b)	✓ Male	90 kgs
B ADVERSE E	VENT OR P	RODUC	T PROBLE	M	
. Adverse Even	t and/or	Pro	duct Problem (e.g., defects/mail	unctions)
Check all that eppi		Event			
Death:	"		Disability :	or Permanent Da	mace
✓ Life-threatenin	(mm/dd/yyyy)		_	Anomaly/Birth C	
✓ Hospitalization	•	nged	_	ious (Important M	
_		-	_	VDamage (Devic	
. Date of Event (mn				Report (mm/dd	
03/0 . Describe Event or	9/2014			03/31/14	
id yo man with with pneumococchen developed tesistant to the tesistant to	ccal bacted severe Correstment of and vance eventually larrhea. Usube (confide duodenum) equired tracking arked 1 fluid a signed antibic (6) Remai	remia, difficient diff	successficile infoo vancomy onemas. eved but cfecal trantobe in 3/06/14. to ICU f of pan-screw E. co and trans spitalized ss).	ully treate ection whicin, IV Complicate ontinued to splant via the 3rd/4tl Diarrhea in or septic susceptible li. Treate	ed, but ch was d by c have n nproved. shock. E. d with
Relevant Tests/Lab	oratory Bate, in	cluding !	Dates	(Continue on	page 3)
lood cultures eritoneal flu	on	(b)	(6) b) (6)		
Other Relevent Historice, pregnancy, smooth	wing end elcono	use, he	ng Medical Con petic/renal dysfu	(Continue on iditions (e.g., elle	page 3)
race, pregnancy, smo	wing end elcono	use, he	ng Medical Con petic/renal dysfu	ditions (e.g. alle	p age 3) rgies,

PLEASE TYPE OR USE BLACK INK

of I 546515 FDA Use Only C. SUSPECT PRODUCT(S) 1. Neme (Give labeled strength & minlabelet) #1 Human stool obtained from OpenBiome (Fecal Microbiota) 2. Dose, Frequency & Route Used Therapy Detes (if unknown, give duration) from/to (or best estimate) #125 mL via Dobhoff tube #103/06/14 4. Diagnosis for Use (Indicable) 5. Event Abated After Use Stopped or Dose Reduced? #1 Severe C. difficile colitis[] #1 Yes No Doesn' #2 Yes No 6. Lot# 7. Exp. Date #1 **Event Reeppeared After** Reintroduction? #2 #2 #1 Yes No Doesn' Apply 9. NDC# or Unique ID Doesn #2 Yes No 10. Concomitant Medical Products end Therapy Dates (Exclude treatment of event) Prior to fecal transplant was treated with po vancomycin, IV metronidazole, and vancomycin enemas (Continue on page 3) D SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Neme 2b. Procode 3. Manufacturer Name, City end State 4. Model # Lot# 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Petient Serial # Other: Unique identifier (UDI) # 6. If Implented, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. In this e Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name end Address of Reprocessor 10. Device Aveilable for Evaluation? (Do not send to FDA) Yes No Returned to Menufacturer on: (mm/dd/yyyy) 1. Concomitant Medical Products end Therapy Dates (Exclude treatment of event) (Continue on pre-2) INITIAL REPORTER

Physician

Yes No

Initial Reporter Also Sent Report to FDA

Yes No Unk.

(Continue on page 3)
Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.



The FDA Safety Information and



Form Approved; OMB No. 0910-0291, Expires: 12/31/2011

reporting of ct problems and product use errors 1/3

See OMB statement on reverse
FDA USE ONLY

A. PATIENT IS	Reporting Program		2. Dose or Amo	unt Frequ	ency Route	
	2. Age at Time of Event or	3. Sex 4. Walght	#1			
(b) (6)	Date of Birth:	224				
(-)(-)	64 Years	Female 234	#2			
In annie de neue	(b) (6)	Male or	· ·			
In confidence	I. EVENT, PRODUCT PR	OPI EM OP EPPOR	3 Detec of Hea /H	unknown, give duratio	n) from 40 5 Eve	nt Absted After Use
Check all that apply:		OBEEM ON ENNOR	(or best estimate)		ed or Dose Reduced?
1. Adverse Even		e.g., defects/malfunctions)	#1 02/21/2014	- 02/21/2014	, #1 🗖	Yes No Does
		ent Menufacturer of Same Medic	ne #2			
2. Outcomes Attrib	uted to Adverse Event		4. Diagnosis or Re	ason for Use (Indica)	tion)	Appl)
(Check all that an	nM (O)		#1 C.Diff Info	ection		nt Reappeared After ntroduction?
The state of the s		ability or Permanent Damage	#2			Yes No Does
Life-threatenin	<i>(mπ/dd/yyyy)</i> g ☐ Con	genital Anomaly/Birth Defect	W2			Appi
☐ Hospitalization	- Initial or prolonged Oth	ar Serious (Important Medical Even	s) 6. Lot#	7. Expiration	n Date #2	Yes No Does
_		Impairment/Damage (Devices)	#1	#1	9. ND(# or Unique ID
3. Date of Event (m		te of this Report (mm/dd/yyyy)	#2	#2		·
02/26/2014		/10/2014	E. SUSPECT	MEDICAL DEVIC	E	
	Problem or Product Use Err		1. Brand Name			
on: The pati	ient was initially s	salvaged in the ICU from	n			
		ith FMT given by EGD.				
		er C.diff recurred and 25 QID, the appropriate	2. Common Device	Name	4	anu -
	asn't responding to					
		performed to insure C	3. Manufacturer No	me, City and State	APP	4 2014
	cause and to rule op- clonoscopy revealed	out other causes of her				A SOM
colitis sugg	esting recurrent se	vere C.diff and FMT was	3			
	then I was asked abo		4. Model #	Lot#		5. Operator of Devic
	with FMT as	yein to 500mg QID and				Health Profession
or go amoun						
			Catalog #	Expiration	m Date (mm/dd/yyy)	/) Lay User/Patient
						Other:
6. Relevant Tests/L	aboratory Deta, Including D	ates	Serial #	Other#		-
			1.52			
			0 1/1 1- 1- 1 01	<u> </u>	15 65 656	
			6. If implented, GN	e Date (mm/dd/yyyy)	/. If Explanted,	Give Date (mm/dd/yyyy)
			8. Is this a Single-u	ise Device that was I	Reprocessed end R	eused on a Patient?
			Yes No		•	
			9. If Yes to Item No.	8, Enter Name and Ad	dress of Reproceese	7
7 Other Relevant Hi	istory, Including Preexisting	Medical Conditions (e.g.				
allergies, race, pre	ignancy, smoking and alcohol	use, liver/kidney problems, etc.)				
	cansplant 02/21/2014 of hypertension.		F. OTHER (CO	NCOMITANT) M	EDICAL PROD	UCTS
	of hyperlipidemia.		Product names and	d therapy dates (exci	ude treatment of eve	nt)
	low back pain.	41				
	obstructive pulmona of pseudomembranous					
7. History	of septic shock fro	m UTI and C. difficile				
8. History	of B12 deficiency.		G. REPORTER	(See confidentia	lity section on t	back)
PRODUCT A	VAILABILITY				-	- 1
	or Evaluation? (Do not send)	product to FDA)				
	Returned to Manufacture	•				
	C. C	(mm/dd/yyyy)				
D SUSPECT PR	RODUCT(S)				1 4	
	lanufacturer (from product la					
1 Name (Fecal I	stoorbies Milubi	075				
Manufacturer:			2. Health Professio	nal? 3. Occupation	10	I. Also Reported to:
Name:			Yes No	Nurse		Manufacturer
Strangth:				nt your identity disclos	ted .	User Facility
Maria de Armania			1 0. 11 you do 1901 was	- your monthly wisches		

B.5. Describe Event or Problem (continued)

... it might assist treatment as it did initially in the ICU. They should have continued her Vancomycin 500mg QID and used the FMT as an adjunctive treatment, not a primary treatment. The treating GI physician however did not continue her Vancomycin after the FMT, thinking that the FMT was enough and it is not. He used the FMT as the primary treatment and that was not the appropriate treatment. After a few days the patient was readmitted with fullminant C.diff colitis. Perhaps she would benefit from emergency surgery immediately, but they waited until morning and the patient died.

Individual Case Safety Report

10079170-01-00-02

B.7. Other Relevant History, Including Presxisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatichenal dysfunction, etc.) (continued)

- ... History of insulin-dependent diabetes mellitus.

 10. History of chronic kidney disease stage III.

 11. Anxiety, depression disorder.

Individual Case Safety Report



ARY reporting of oduct problems and use errors

Form Approved OMB No 0510-0291, Expires 6/30/2015 See PRA statement on reverse

FDA USE ONLY Triage unit sequence #

Adverse Event Reporting Program P	age 1 of 🗾		
A. PATIENT INFORMATION	2 Dose or Amount	Frequency	Route
(b) (6) 2 Age at Time of Event or Date of Birth: 2 years old Female 23.	42	once	via colemostopy
In confidence	кд][
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Theck all that apply:	3 Dates of Use (If unkr (or best estimate)	nown, give duration) from/to	5. Event Abated After Use Stopped or Dose Reduced?
Adverse Event Product Problem (e.g., defects/malfunctions)	#1 4:4/2014	•	#1 Yes No Doe
Product Use Error Problem with Different Manufacturer of Same Med	icine #2		#2 Yes No Doe
Outcomes Attributed to Adverse Event (Check all that epply) Death: Disability or Permanent Damage	4. Diagnosis or Reason #1 Recurren* C.		8 Event Reappeared After Reintroduction?
(mm/od/yyyy) Life-threatening Congenial Anomaly/Brth Defect	#2		#1 Yes No Doe
☐ Hospitalization - initial or prolonged ☐ Other Senous (Important Medicat Evi	ents) 6 Lot#	7. Expiration Date	#2 Tyes TNo TDoe
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1	#1	9 NDC # or Unique tD
Date of Event (mm/dd/yyyy) 4 Date of this Report (mm/dd/yyyy)	#2	#2	
04/11/2014 05/01/2014	E. SUSPECT ME	DICAL DEVICE	
Patient underwent a fecal microbiota transplant (FMT	1 Brand Name		
for a history of recurrent C. difficile on the morni of 4/4/2014. His CBC that afternoon showed a	rig		
plainlet count of 89,000. (b) (6) later (on	2 Common Davice Nar	ne	2b Procode
(b) (6) he developed intechiae and was found to has platelet count of 28,000. He required mospital		Street Louis	
admission for platelet transitusion.	3. Manufacturer Name,	City and State	
7.			
	4 Model#	Lot#	5. Operator of Devi
			Health Professio
CIU	Catalog #	Expiration Date (n.	nm/dd/yyyy) Lay User/Patient
Relevant Tests/Laboratory Data, including profile			Other:
Platelet counts:	Serial #	Unique Identifier (UDi)#
4/4/2014: 89,000 (b) (6) 26,000			
MAY 1 3 2014	6. If Implanted, Give Da	te (mm/dd/yyyy) 7. If Ex	cplanted, Give Date (mm/dd/yyyy
.•	8. Is this a Single-use D	evice that was Reprocess	sed and Reused on a Patient?
	Yes No	ter Name and Address of R	
Other Balancet Ulabour Instead to Bassis And Advisor On the Control of the Contro		ter manie and pouress of K	shioce2201
Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and aicohol use, liver/kidney problems, etc.)			
Intlammatory Bowel Disease Recurrent C. difficile	F OTHER (CONC	OMITANT) MEDICAL	PRODUCTS
(b) (6)	Product names and the	rapy dates (exclude treatm	ent of event)
A - 9			
	G. REPORTER (Se	e confidentiality sect	ion on back)
PRODUCT AVAILABILITY	/		101
oduct Available for Evaluation? (Do not send product to FDA)			
Yes No Returned to Manufacturer on:	_		
SUSPECT PRODUCT(S) (mm/6d/yyyy)			
Name, Strength, Manufacturer (from product label)			
Name' Studi from healthy conor used for FMT Strength:			
Manufacturer	2. Health Professional?	3 Occupation	4 Also Reported to:
Name	Yes No	Etysician	☐ Manufacturer
Strength:	5. If you do NOT want you	_	User Facility
Manufacturer. RM FDA 3500 (2/13) Submission of a report does not constitute an	to the manufacturer, pla		Distributor/importe



UNTARY reporting nts, product use error

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse

oduct blems and	Tribuna conti	DA USE ONLY
use errors e 1 of Z	sequence #	64281
- F		
2. Dose or Amount #1 25 mL	once	nasogastric tube
9 #2		
(or best estimate)	nown, give duration) from/lo	5. Event Absted After Use Stopped or Dose Reduced? #1 Yes No Doses
#1 6/26/14 #2		Apply
4. Diagnosis or Reaso	n for Use (Indication)	#2 Yes No Doesn
	difficile colitis	8. Event Reappeared After Reintroduction? #1 Yes No Doesn
#2		Apply
⁶ , (b) (6)	7. Expiration Date	#2 Yes No Doesn
	- 01	9. NDC # or Unique ID
#2	#2	
E SUSPECT ME	DICAL DEVICE	
I Brond Name		
		T
2. Common Device Na		2b. Procode
		TU
3. Manufacturer Name,		
	SEP 1	5 2014
4. Model #	Lot#	5. Operator of Device Health Professions
Catalog #	Expiration Date (m	Den/dd/yyyy) Lay User/Petient Other:
Serial #	Unique Identifier (
6. If Implented, Give Da	ate (mm/dd/yyyy) 7. If Ex	cplanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use I	Device that was Reprocess	sed and Reused on a Pationt?
9. If Yes to Item No. 8, E	nter Name and Address of R	eprocessor
7]		
E OTHER COME	YOMET A NEW MERCHAN	PRODUCTS
and the second s	OMITANT) MEDICAL	
See p. 3	stopy action (oxedes acts).	on or every
e DEDOCTED (S	se confidentiality sec	for an hadri
C. MERCINIES ICI	sa Germaniania See	(OIT OIT DAGEN)

Adverse Event Reporting Program

A. PATIENT INFORMATION	ent or 3. Sex 4. Weight	2. Dose or Amoun			
1 Patient Identifier 2. Age at Vime of Even (b) (6)	ent or 3. Sex 4. Trought	25 ml	once	nasc	ogastric tube
(b) (6)	Female Ib				
	✓ Male or kg	#2			
In confidence					
B. ADVERSE EVENT, PRODUC	T PROBLEM OR ERROR	3. Dates of Use (If un (or best estimate)	known, give duretio		vent Absted After Use oped or Dose Reduced?
Check all that apply:		#1 6/26/14			Yes No Doesn'
	blem (e.g., defects/malfunctions)	40			Apply
Product Use Error Problem with	n Different Manufacturer of Same Medicine			#2 [Yes No Doesn'
2. Outcomes Attributed to Adverse Even	nt	4. Diagnosis or Reas		ion)	Apply
(Check all that apply)		#1 Recurrent C	difficile		vent Reappeared After eintroduction?
Death:	Disability or Permanent Damage	#2		_	Yes No Doesn'
	Congenital Anomaly/Birth Defect	,			Apply
Hospitalization - initial or prolonged	Other Serious (Important Medical Events)	6.104	7. Expiratio	n Date #2	Yes No Doesn'
Required Intervention to Prevent Per		(b) (6)	#1	9 NI	DC # or Unique ID
		#2	#2		
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	E QUADECTIO		7=1	
07/31/2014	09/02/2014	E SUSPECT M	EDICAL DEVIC	7.5	
. Describe Event, Problem or Product U	ae Error	1. Brand Name			
The nationt is a 22 year a	1d man with C-5 quadriplegia				
since a MVA in (b) (6)	He had multiple	2. Common Device N	lame	1	2b. Procode
	e since November 2013 after				
receiving an antibiotic for				CTU	
required hospitalization for infection. He was treated to		3. Manufacturer Nam			
vancomycin, including a van				SEP 1 5 20	14
difficile PCR was positive	on 5/5/14. Stool studies on			- 10 50	14
6/2/14 revealed no pathoger		4. Model #	Lot#		5. Operator of Device
campylobacter antigen, negative Cryptosporidium EIA negative		, woder w			Health Professions
positive.	ve, c. diriterit ren				L realth Professions
-		Catalog #	Expiration	n Date (mm/dd/yy	(77) Lay User/Petient
					D Owner:
. Relevant Tests/Laboratory Data, Include	ding Dates	0.000			Other:
	/13/14, 2/25/14, 4/24/14 and	Serial #	Unique le	dentifier (UDI) #	
6/30/14 were all negative i	for stool O&P and Giardia				
	nBiome archives an aliquot	6. If Implented, Give I	Date (mm/dd/yyyv)	7. If Explanted	Give Date (mm/dd/yyyy)
of stool from every donation and stool O&P and Giardia					
on the stool sample that wa			Device that was i	Reprocessed and	Reused on a Patient?
transplant.		Yes No			
		9. If Yes to Item No. 8,	Enter Name and Ad	dress of Reproces	sor
. Other Relevant History, Including Pres	visting Madical Conditions (s.s.				
allergies, race, pregnancy, smoking and a	sicohol use, liver/kidney problems, etc.)				
Past medical history positi		F. OTHER (CON	COMITANTIM	EDICAL PRO	DUCTS
osteomyelitis at donor ilia bowel and bladder, and GER		Product names and to	The state of the s	AND THE PERSON NAMED IN	CONTRACTOR SE
Dower and Disduct, sau GERL	· ·	See p. 3			
		G. REPORTER	San and Adams	Ofen comple	Boodhi
		S MERINIEN &	rea conninante	MA SECTION OF	(OGICIA)
PRODUCT AVAILABILITY					
Product Available for Evaluation? (Do not	t send product to FDA)				
Yes No Returned to Manu	ufacturer on				
	(mm/8d/yyyy)				
SUSPECT PRODUCT(S)				THE PERSON	
Name, Strength, Manufacturer (from pro	iduct label)				
Name: Human stool Strength:	1				
Manufacturer OpenBiome		12. Hearn Promasiona	171 J. Occupation		(4. Also Reported to:
		Yes No	Physician		Manufacturer
Name: Strength:					User Fecility
Manufacturer:		If you do NOT want ; to the manufacturer,			Distributor/Importer
ORM FDA 3500 (2/13) Submi	ission of a report does not constitute an adm	ussion that medical pers	connel or the produc	of caused or contri	thuted to the event



(CONTINUATION PAGE) OLUNTARY reporting of events and product problems

Page 3 of 3

Adverse Event Reporting Program

B.5. Describe Event or Problem (continued)

He underwent fecal transplant on June 26, 2014 using donor stool from OpenBiome (donor bepecimen (b) (6) Despite the transplant he continued to have diarrhea. Subsequent testing on 7/31/14 revealed that his stool Giardia antigen was positive and stool C. difficile PCR was also positive. He was then treated with a course of metronidazole. Repeat testing on on 8/21/14 showed that the Giardia antigen was now negative, and C. difficile PCR was negative on 8/25/14. I spoke with the patient's mother this morning and she tells me that his diarrhea has resolved. This raises the question as to the source of the Giardia infection and whether the donor stool may have been the source. The patient has no recent travel history and has not drank water from any streams. Water is supplied to his home by a private company (they do not have city water and do not have a well). The patient's mother has discussed this with the local health department. With regards to the donor, screening has been performed every 2 months since January 2014 (see below) and all screening tests have been negative, including stool O&P exams and Giardia (b) (4)

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Routine donor testing on 1/13/14, 2/25/14, 4/24/14 and 6/30/14 were all negative for stool O&P and Giardia (b)(4) Moreover, OpenBiome archives an aliquot of stool from every donation. The aliquot was pulled and stool O&P and Giardia (b)(4) were both negative on the stool sample that was used for this patient's transplant.

B.7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepaticirenel dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

baclofen, bisacodyl, dantrolene, docusate, famotidine, levalbuterol, loratadine, lorazepam, multivitamin, ondansetron, oxandrolone, oxycodone, promethazine, senna

DS\$ SEP 1 5 2014

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Fax: +1 (800) 332-01	Fax:	+1	(800)	332-0	17
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Page 2 of 9 09/19/2014 6:46

Form Approved	OMB No	0910-0291, Expires	6/30/201
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r use by user-facilities, listributors and manufacturers ANDATORY reporting

Mir Report #	(b) (6)	ee OMO statement on revers
UF/Importer Re	port#	
12.	KERR	· ·

	0-	<i>- O</i> .)	FOR USE ONLY
C. SUSPECT PROD	UCT(S)				-11
 Name (Give labeled street #1 OpenBiome 30ml 		ohioro	Dran-	ration	
	recal MICI	ODIOE	Prepa	tation	
#2 2. Dose, Frequency & Rou	ita Used	3 33	Dr. Datas	H unknown	nius disensiami
#130mL, Once, J-		from/to	for best	estimate)	give duration)
	Twoe		08/201	.4	
#2 4. Diagnosis for Use (India		#2	C =		
#t Refract., svr		CDI		Abated Afte ed or Dose i	Reduced?
#2			WI 🗀 1	res No	Doesn't
6. t nt #	7. Exp. Date		#2 🔲 1	es No	Doesn't
(b) (6)	#1 02/07/2	014		Reappeared	
H2	W2		_	oduction? 'es \[No	Doesn'i
9. NDC# or Unique ID	1			es 🗀 140	App!y
			#2 🔲 1	es No	Doesn't
10. Concomitant Medical F					
Chemotherapy for glucocorticoids;	Anti-C. dif:	ficile	antibi	otics i	ncluding
metronidazole, va blood pressure su	ncomycin, f	idaxom	cin; I	evophed	for
Divod presoure ou	фроге		(0	ontinue or	page 3)
D SUSPECT MEDIC	AL DEVICE				
1. Brand Name					
2. Common Device Name			2b. P	rocado	
3. Manufacturer Name, Cit	y and State				
4. Model #	Lot #			5. Operator	of Davice
Catalog S	Expiration D		dali	Health	Professional
Catalog 6	Equation	ata funio	JUYYYY)	Lay Us	ar/Patient
Serial #	Unique Iden	ther (UDI) #	Other.	
6. If Implanted, Give Date (mm/dd/yyw)	7. If Expla	inted Giv	Date (mm/	ndAvaa)
8. Is this a Gingle-use Devi	ce that was Repro	cossed ar	rd Rouse	on a Patier	117
9. If Yes to Item No. 8, Ente	or Name and Addre	es of Rep	rocessor		388
				OF	2 2 20
				SEL	2 2 ZU
10. Device Available for Ev	alustion? (Do not a	end to FD	A)		
Yes No [Returned to Ma		•		
11. Concomitent Medical P	mducts and Thorn	Deter	(Fush.de	(mm/dd/y)	
T. Concountant medica P	LOUGHS SERVING LIVERS	ibà maras	(EXCIDE	irçameni or i	event)
E INITIAL REPORTE	ER.		(C	ontinue on	page 3)
		-			
				0 1	
12		1			
2. Health Professional? 3.			4. lr	sport to FD	Also Sent
Yes No P	hysician			Yes N	_

A. PATIENT IN	FORMATION			
Pariant Identifier			3. Sex	4. Weight
) (6)	of Event: 80	Years	√ Female	lb
	Date		Male	Or
In confidence	of Birth:			kg
B. ADVERSE E	VENT OR PRODU	CIPROBLE	M	
Adverse Ever	nt and/or Pro	oduct Problem (e	.g., defects/malfi	unctions)
Outcomes Attribu	ited to Adverse Event			
Death:	(b) (6)	Disability of	r Permaneni Dar	mage
Life-threatening	(ກໍການບໍ່ພາງນັ້ງ <i>ງາງ)</i> —	Concenita	Anomaly/Birth D	efect
	n - initial or prolonged		ous (Important M	
	rvenilon to Prevent Perm			
Date of Event (mi			Report (mm/dd	
	11/2014		08/11/2014	
Describe Event or		•		
	iple major come and severe, o			
	probability of	•		
esponse to F	MT via GJ on ba			
vents was re	ported.			
riefly, ongo	ing respiratory	failure i	n rehabili	tation
cility (leg	oniella versus	CHF) and t	ransferred	to
	diagnosis of p			
_	ectrum antibiot			
	ANAGERIC	A'		
carrey. CD1	positive and c	linical pi		
mplicated C	DI including tr	ansient ile	cture of se	evere, toxic
omplicated C egacolon on	DI including tr CT. Patient tre	ansient ile	cture of se eus but no Vanco PO/PI	evere, toxic R,
omplicated C egacolon on agyl and Fi	DI including tr	ansient ile ated with v ut benefit,	cture of seeus but no Vanco PO/PI	evere, toxic R,
omplicated C egacolon on lagyl and Fi vidence of S	DI including tr CT. Patient tre daxomicin witho	ansient ile ated with v ut benefit,	cture of seeus but no Vanco PO/PI	evere, toxic R,
omplicated C egacolon on lagyl and Fi	DI including tr CT. Patient tre daxomicin witho	ansient ile ated with v ut benefit,	cture of seeus but no Vanco PO/PI	evere, toxic R,
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 8

FDAUSE ONLY

2. # Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation 4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use? Yes

Initial Use of Device Reuse Unknown

H action reported to FDA under
 USC 360(f), liet correction/
removal reporting number:

1f. Corrected Date

No

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614 (8 8180 0 10 10 10 1	1046911			EBIASO A BIA	Page 2	of 8	5	Cox	503	2	∇
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1 Check One] 2. t	JF/Importer	Report Number		1. Type of Reportable	Evant	12	# Follow	-up, V	Vhai
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3. User Facility or Imp	ocrter Name/A	ddress				Serious Injury			=	dibona	
						Malfunction		- 1	_		
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						3. Device Evaluated by	Manufacturer?	4.	Device N	Aanufa	actui
						Not Returned to	Manufacturer		(mm/yyy)	V)	
4. Contact Person			5. Phone I	Number			uation Summary Attache	ed			
							e to explain why not) or		Labeled	for Si	nale
6. Date User Facility of	r 7.	Type of Repo	rt .	8. Date of This R	enort	provide code:	e to explain why hot) of		2200100	101 011	-igit
Importer Became Aware of Event (mm			•	(mm/dd/yyyy)					Ye	\$	
Kware or Event (man	- L	Initial		1		6 Front Droblem and I	Industries Codes (Dole				
		Follow-up #		_		6. Event Problem and I		r to cooin	g menue)		
9. Approximate	10. Event Pro	blom Codes	Refer to coo	ling manual)		Patient Code	-		-		
Age of Device	Patient					Device					_
	Code		-	-		Code	-		-		
	Device									7.	
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11. Report Sent to FDA	A? 1	2. Lecation V	Vhere Event	Occurred						آ آ	
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No (mm/dd/	(WW)	Home		Diagnostic I	Facility	Condusions			-	7_[
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13. Report Sent to Man	nutracturer?		ient Trealme	_	Carry	7. If Remedial Action in	Itlated, Check Type	8. Use	ge of De	dçe	
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14. Manufacturer Name	esenppAvo					Relabeling	Modification/	9. H ac	ction repo	rted t	o FD
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G. ALL MANUFAC	Contract Charge										
t. Contact Office (and i	Manufacturing	Site for Devi	cea)	2. Phone Numbe							
Name				617-575-220	1						
OpenBiome Address				3. Report Source	an abd						
Managa				(Check all that	⇒Pγ)						
/1.\	/ 4			Foreign							
(n)	(41)			Study							
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Email Address	н "чун			Consumer							
	10 050			Health Profes	sional						
safety@openblom				User Facility							
 Date Received by Menufacturer (mm/dd 	thought	5. (4)NIDA N		Company							
09/04/20		(A)NDA #		Representativ	e						
		IND#		Distributor							
6. If IND, Give Protocol	¥	BLA #		Other:	1						
				,	i						
7. Type of Report		PMA/ 510(k) #									
(Check all that apply)		Combination									_
5-day 30-day		Product	Yes								SE
7-day Period	lic ,	Pre-1938	Yes								-56
10-day Initial			_]						
15-day Follow	-up #	OTC Product	Yes								
9. Manufacturer Report	Number 8	. Adverse Eve	nt Termie	J							

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing tristructions, searching existing date sources, gathering and meintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other espect of this collection of information, including suggestions for reducing this burden to:

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PRAStaff@ide.hhs.gov
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(CONTINUATION PAGE)
or use by user-facilities,
distributors, and manufacturers
MANDATORY reporting

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FORM F	FDA 3500/	A (2/13) ((continued,
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Back to Item B.5

Back to Item B.6

Back to Item B.7

Back to Item D.11 Back to Item C.10

After informed consent by daughter (b) (6) FMP 30 via GJ after 4L PEG and pre-PPI with 8 hour d/c of anti-CDI therapy. No clinical response was noted and continued clinical decline. Two days post-FMT flexible sigmoidoscopy conducted to rule out ischemic and CMV colitis, and evidence of pseudo-membranes detected (note: no endoscopy conducted at time of diagnosis). Ongoing hypotension and clinical decline. Family requested withdrawal of active treatment with comfort care measures only, and patient expired. Cause of death believed to be multifactorial including respiratory failure and CDI. No objective adverse events from FMT were noted.
B.6. Relevant Tests/Laboratory Data, Including Dates (cortinued)
B.7. Other Relevant History, Including Presxisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) 4. Recurrent CDI
- Approximately 6 episodes each following antibiotics most commonly for pneumonias
- Previous treatments include: Flagyl, Vanco and Vanco taper
- Vanco suppressive therapy initiated in rehab for unclear time period but negative CDI test and thus discontinued at some point prior to admission
Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)
DSS
DSS SEP 2 2 201
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Other Remarks

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Form Approved OMB No. 0910-0291, Expires: 6/30/2015 ee OMB statement on reverse.

use by user-facilities, istributors and manufacturers NDATORY reporting

(b) UF Amporter Report #

FORM FDA 3				Pag
A PATIENT I	The second burneling of			
(b) (6)	2. Age at Time of Event:		3 Sex	4. Weight
In comidence		(6)	Male	O;
	EVENT OR PRODU		Й	
1. Adverse Ev		oduct Problem (c.		
	uted to Adverse Event	Product Fredom (c.	s., dereas/man	incuonsj
Death:		Disability or	Permanent Dar	nage
Life-threater	(min/da/yyyy) ing	Congenital .	Anomaly/Birth D	efect
	on - initial or prolonged		us (Important Me	
	ervention to Prevent Perm	anent impelment	Damage (Device	es)
3. Date of Event (m	m/dd/yyyy) 31/2014	4. Date of This !		mmi
5. Describs Event o			09/19/2014	
Index 3) and CDI non-respo PCR on backgr Giardia antic EIA, culture. diarrhea. Re- stool Giardia of metronidaz	paraplegia and Giardia followinsive to standa cound of negative, Campylobact Underwent FMT tested (Day 35 antigen and CD ole and repeat with subsequent	ng FMT. Bri rd therapy e stool stu- er antigen, via NG but coost-FMT) au I PCR. Treat testing for	efly, recu with posit dies inclu Cryptospo continued and positiv ted with c	rrent live CD ding ridium to have
Continued on page	3	SEF	CT U 2 2 2 201	4
		10	Continue on p	15 ara
. Relevant Tests/Lab	orstory Dats, Including	Dates		age of
kegular donor 04/24/2014, ar	testing on 01/1 d 06/30/2014 we	3/2014, 02/3	25/2014,	+001
Jva/Parasite a	nd Giardia (D)(4) The	a cammla u	2 6
pefore and aft	4/15/2014, with er collection.	negative se	creening r	esults
rozen aliquot	this regular to of every outgo investigations o	ng sample to f potential	to allow	d
Other Relevant Histories, pregnancy and	ory, Including Preexisting	g Medical Condit	ions (e.g., silerg	ige 3)
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eurogenic blac enna, docusate	der and bowel t	reated with	bisacodyl	
. Femoral DVT				j
. Osteomyellti . GERD	s at donor ilia	c graft sit	e	
Recurrent CD				
spitalization	rrences (>3), in , after antibion	ncluding l lics for UT	I	
		(00	ontinue on pa	ge 3)
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of 25	K	05	189	11	
C. SUSPECT PROD			27		FDA Usa Only
Name (Give labeled street)					
#1 OpenBiome 30m	L recal Mici	obiota	Prepa	aration	
#2 2 Doss, Frequency & Ros	an Mari	T. =			
		1/Om/	o (or best	estimate)	, give duration)
#125mL, Once, NO	Tube	#106,	/26/20:	14	
#2 4. Diagnosis for Use (India	-dli	#2	-		
#1 Recurrent C. o		litie		t Abated AP ood or Dose	
W2			#1	Yes No	Doesn'i
614	7. Exp. Date		#2 []·	Yes No	Doesn't
(b) (6)	#1 12/10/2	014	8. Event	Reappeare	
#2	#2 .		Reint/	oduction?	Doesn'l
9. NDC# or Unique ID			», []	res No	Apply
				res No	— Apply
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levalbuterol, lor	atadine, lar	azepan	, mult	ivı tami	D
ondansetron, oxan	drolone, oxy	codone	, pron	methazin	e, senna
			(C	ontinue o	n page 3)
D. SUSPECT MEDIC	AL DEVICE				
Brand Nome					
Common Device Name			2b. P	recods	
Manufacturer Name, City	and State			-	
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Catalog #				_	Professional
Cabing #	Expiration De	te (mm/dk	imm)	Lay Us	er/Patient
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s this a Single-upa Device	that was Reproce	essed and	Reusod	on a Patien	17
If Yes to Rem No. 8, Enter	Name and Addres	of Repr	oceanor		
Device Available for Eval	uzition? (Do not see	nd in FDA			
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Concomitant Medical Pro-	durts and Thoran	Dates #		(mm/dd/yy)	W
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Asim Profession In 19		-			
conth Professional? 3. Or	sician		Rep	al Reporter ort to FDA	Also Sent

Yes No Unk

Sul Submission of a report does not constitute an admission that medical parsonnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

7. Typz of Report

Initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

[] Importer

3. User Facility or Importer Name/Address

2 UFAmporter Roport Number

5. Phone Number

12. Location Where Event Occurred

Hospite!

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report (mm/dd/yyyy)

Outpatient Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

617-575-2201

Foreign Study Literatura Consumer

3. Report Source (Check all that apply)

Health Professional

User Facility

Distributor

Other.

Company Representative

I. Chock One

User Facility

4. Contact Person

6. Date User Facility or

11. Report Sent to FDA?

Yes _

No

Yes

No

Name

Address

OpenBiome

Email Address

safety@openbiome.org 4. Data Received by Manufacturer (mm/dd/yyyr)

6. M IND, Give Protocol #

5-day 30-day

7. Type of Report (Check all that apply)

7-dey

10-day

09/04/2014

Periodic

Inital

15-day Follow-up# 9. Menufecturer Roport Number

Importer Became Aware of Event (mm/dd/yyyr)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer NemelAddress

G ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

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(A)NDA #

IND #

BLA # PMA/ 510(k) #

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

Yes

Yes

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(CONTINUATION PAGE) or use by user-facilities, distributors, and manufacturers MANDATORY reporting

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FORM FDA 3500A (2/13) (continued)

OF Danadh	F		
B.D. LISSELTING	P-MOTIT	AT PAGAIOM	(CONTINUED OF
8.5. Describe		O) I I O DICKE	(CONTENTIONO)

Back to Item

Back to Item B.7

Back to Item D.11 Back to Item C.10

Successive donor testing has been pan-negative and safety aliquot used for patient's FMT negative for stool C&P and Giardia (b) (4) Patient had no recent travel/camping history or ingestion of any water from streams. Unclear ir any rehabilitation pool exposures. Patient does have wells but water supplied by private company and local public health department inquiring.

Given safety sample used in actual FMT was negative for O&P and Giardia it seems unlikely the source of the event. The possibility of a false positive Giardia test (with ongoing CDI) or an environmental source exposure is possible given the clinical context.

S.O. Helevant Tests/Labors	fory Data,	Including	Dates (continued)	
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adverse events. Upon learning of the possible AE from (b)(6), OpenBiote pulled the safety aliquot and sent it to a CLIA-certified laboratory for stool O&P and Giardia (b)(4) both of which were

(b) (4) tests for Giardia, (b) (4) and Ova/Parasite were performed on safety aliquot of stool for Donor (b) (6) Specimen (b) (6) Tests were performed on 08/30/2014. Results were as follows: (1) Ova + Parasite Exam: "No ova, cysts, or parasites seen."
(2) Giardia lamblia (b) (4) "Negative"
Please see attached test results for supporting documentation.

8.7. Other Relevant History, Including Pressisting Medical Conditions (e.g., ellargies, race, pregnancy, smoking and alzohol use, hapatic/renel dysfunction, etc.) (continued)

Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 end/or D.11; placed distinguish)

Other Remarks

CBER

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adverse events, product problems and product use errors

Fern Approved: OMB No. 0816-0861, Empireo: 8/30/2016 Bee PRA exament en reverso.

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	(b) (6) Sers old	✓ Fernal	97 15			
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3. Date of Event (m	• • • •	4. Date of this Repor	(mm/payyyy)	92	102	
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. Describe Event	Problem or Product L	no Rivor		1. Brand Name		
prior hospi	talization and e	for FMT study	pased on	Fecal Microbiot	a Transplant	
At appointme	ent, patient's c	Warell well-hot	AR WAR	2. Common Dovice Herr	0	20. Presente Citol
reported as	"fair." Patier	nt completed FMT related donor.	procedure	Stool Transplan		THE ALBERTA ON 1 CT.
completed 24	-hour follow-up	phone call on	24-301-2014			EEDIAN
Patient was	experiencing al	ight farigue or	d seewered	11/6/16	1/ /6/	11/203010
negatively s	for fever, suctor	inal pain, naus	CA,)). (())	(4)
Jul-2014, pa	tient's daughte	r completed 1 ev	PARTAN	(1.5)	/, (-)	(-)
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MEDWATCH

FOF VULUNTARY reporting of adverse events and product problems

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Page 3 of 3

The FDA Sefety Information and Adverse Event Reporting Pregram

weapled Exert Methodelia Liestian
B.S. Domenino Event er Prehism (continued)
Patient had experienced formed bowel movements. On 9/15/2014, patient completed a follow-up appointment and noted occasional increased gas. Patient's well-being was reported as "good." Vitals signs were BP (123/64) and bulse (60) Patient was advised to try simethicone (Gas X) for gas/bloating. Between (b) (6) patient was hospitalized for congestion and evaluation of altered mental
status. Patient was having dinner and appeared to be 'glazy eyed', therefore, patient was transported to ER department. Neurology was consulted and symptoms were thought to be secondary to complex partial seizures. A CT scan was obtained and patient was started on IV antibiotics and admitted to medicine floor for further evaluation. CT scan did not have any clinically significant changes. Patient was started on Depakete to help with neurological symptoms and discharged. On $(b)(6)$ Infectious Disease was contacted because patient developed a temperature (99.60f) with lethergy and dahydration. Patient was started on IV fluids and instructed to start vancomycin and ceftazidine. Patient continued to develop more connection and began developing trouble swallowing thin and thick liquids. Patient was hospitalized $(b)(6)$ and discharged on $(b)(6)$ Patient passed away on $(b)(6)$ upon calling to complete 6-month phone call on 20-Jan-2015, research staff was informed that patient had passed away. Based on patient's previous medical history and lack of abdominal/bowel symptoms during post-FMT hospitalizations, it is unlikely that the adverse event is related to study procedure or FMT.
B.6. Relovent Testo/Lebeselary Data, Including Dates (continues)

8.7. Other Relevant Missory, Including Presticting Medical Conditions (e.g., ellergies, race, programmy, amering and electral use, hopescrenal dyelunction, etc.) (continued)

F. Concernant Medical Products and There are Dolon Products treatment of event (conducts)

Depakote (10/14/2014 - (b) (6)
Torsemide (11/21/2013 -

DS\$

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NEDWATCH	For VULUNIARY reporting of adverse events, product problems and product use errors
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(Check of that as	(6) (6)			Infection		ichle		Hereanthau	7
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☐ Hazzitelizeria	n - Initial or prolonged 🔲 Oil	hor Barleus (Impona	ni Medical Events)	6. Loi Ø	7.	Expiration D] Yes □ N	PARPLY
Required Ime	rventen to Prevent Parmener	d impalment/Demag	(Devices)	81			e. Ni	oc s or Unles	e iD
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Denesion Prient	Problem of Product Use Es	707		1. Brend Name Facel Micro	biota Tr	onsplant			
Patient was	screened for INT s the INT procedure on	tudy 25-Nov-2	uis, and using a						
non-related	donor. At 24-hour	follow-up pho	DB CELL,	2. Common David				Zo, Precede	CTU
MATSONS WAS	experiencing mild	fatique. Dev	ghter	Stool Trans	plant				داً) لا هم
boantes1192	rion, abdominal pai	n. loss of ap	petite,	& Manufacture M	mana 1964 me	a Sea		FEI	3 1 0 201
constinutio	on, diarrhea, fevera	. chills, or	mauses. At	(h) (6)	(h)	(4)	· L	1 0 701
mild blosts	low-up phone call, p ing/gam/abdominel di	econfort. On	26-	(D)	Ο),	(0)	(4)		
Tan-2014. E	etient completed 4-	week follow-t	p visit,	A. Model 0		Lard	, ,	6. Opera	tar of Dovice
and caregiv	ver reported that pa	fleut, # stoor	eit no	N/A		N/A		/ Heat	n Professional
formed, appetite was excellent, and there were no recent hospitalizations			-		Contratta a P	lata (mavady	446 D 1 841	Je Mailen	
				Caming 6		N/A	and lunia Ama		
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6. Reisvent Tools	Lob aretary Date, including	Dates		Berial 8		Unique iden	HROT (UDI) Ø		
recal Lacto	cterrin (04/26/2014) Le Detection PCR (04	1/26/2014) - P	egative	N/A		\$47.65			
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	act infections			Product names o	nd therapy a	dates (exclud	treatment of	event)	
C. Diffici:	on			Levothyroxins (12/23/2013 - (b) (6) Warfarin (1/7/2014 (b) (6)					
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MEDWATCH

For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

Adverse Evert Reporting Pregram

8.5. Decerto Evert or Preblem (continued)

Patient completed a second follow-up appointment on 25-Nar-2014 due to complaints of weakness. Sowel movements were now semi aclid and more frequent. Patient developed an infection of the right calf and was placed on topical antibiotics. In addition, caregiver noted that patient had an increased pulse rate and that patient was now in hospice. Patient was noted has having tachycardis and it was recommended that patient was taken to ER; however, daughter declined since patient had hospice status. Patient's daughter was asked to follow-up with PCP for rapid heart rate. Vital signs were BP (123/97) and pulse (157). On (b) (6) patient presented to clinic for wound assessment. Upon arrival to office, patient was not responsive. Patient was evaluated (no pulse was found) and patient was pronounced decessed upon arrival. Sub-investigator began calling subject for 6-month follow-up in June 2014, however, patient's family was unresponsive to research staff calls. Patient was marked as lost to follow-up until January 2015 when research staff checked patient's ZMR and noted that patient was decessed.

Based on patient's medical history and concomitant illnesses (right leg infection, left leg ulcer, urinary infections), it is unlikely that the adverse event is related to study procedure or intervention (FMT).

B.A. Relevant Tests Laboratory Date, Including Dates (continued)

B.7. Other Retovent History, including President Modical Conditions (e.g., ellergios, reco, pregnancy, emolting and electric use, hepetiational dystanction, etc.) (cordinated)

F. Concomitant Medical Products and Therapy Dates (Exclude transment of event) (continued)

Metroprolo1 [12/30/2013 (b) (6) Risperidons (1/7/2014 - (b) (6) Transdol (12/5/2013 - (b) (6)

Transdol (12/5/2013 - (D) (O)
Cholecalciferol/Vitamin D3 (11/2/2013 - (b) (6)

Ascorbic Acid (10/3/2013 | (b) (6) Kirtazapine (9/25/2013 | (b) (6) Omeprazole (9/4/2013 | (b) (6) Collagenace (12/26/201; DSS

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RY reporting of

Form Approved: OMB	No. 0910-0291, Expire	s. 12/31/2011
	See OMB stateme	mi on reverse

ict problems and	Torne unit	2020000
errors	sequence# 5	82873
2. Dose or Amount	Frequency	Route
#1		
#2		
#2		
Dates of Use (If unknown (or best estimate)	vn, give duration) from/to	5. Event Abated After Use Stopped or Dose Reduced?
#1		#1 Yes No Doesn'
#2		Apply
4. Diagnosis or Reason f	or Use (Indication)	#2 Yes No Doesn' Apply
#1		8. Event Reappeared After Reintroduction?
#2	· ·	#1 Yes No Doesn'
#2		Apply
6. Lot#	7. Expiration Date	#2 Yes No Doesn't
#1	#1	9. NDC # or Unique ID
#2	#2	
E. SUSPECT MEDI	CAL DEVICE	
1. Brand Name		
2 Comment Devil - No.		
2. Common Device Name		CTU
		610
3. Manufacturer Name, Cl	ty and State	FED 1 .
		FEB 1 1 2015
		1
4. Model#	Lot#	5 Operator of Device
		Health Professional
Catalog #	Euplandlau Data (a.	
Catalog #	Expiration Date (mi	TVOOYyyy) Lay User/Patient
		Other:
Serial #	Other#	
. If Implanted, Give Date	(mm/dd/www) 7 lf Fyr	otanted, Give Date (mm/dd/yyyy)
		planted, Give Date (milacoyyyy)
	rice that was Reprocesse	ed and Reused on a Patient?
Yes No		
. If Yes to Item No. 8, Enter	r Name and Address of Re	processor
		•
OTHER (CONCO		
roduct names and therap	ny dates (exclude treatme	ent of aveni)
See page for com	prete text	
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1		
REPORTER (See	confidentiality section	on on backy
Name and Address		
h) (2./	h \ / / / \

Distributor/Importer

.

Adverse Event Reporting Program A. PATIENT INFORMATION

1. Patient Identifier | 2. Age at Time of 2. Age at Time of Event or Date of Birth: (b) (6) 119_{lb} ✓ Female (b) (6) Male B. ADVERSE EVENT PRODUCT PI Check all thet apply: 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Check ell that apply) Death: Disability or Permanent Damage Life-threetening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damege (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 02/02/2015 02/10/2015 5. Describe Event, Problem or Product Use Error See page 2 for complete text. TYPE OR USE BLACK INK 6. Relevant Tests/Laboratory Data, Including Dates PLEASE Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page for complete text. C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufecturer on: (O), (D)(mm/od/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufecturer (from product label) #1 Name Fecal Transplant Strength: Menufacturer 2. Health Professional? 3. Occupation 4. Also Reported to: #2 Name: Yes No Medical Doctor (Physician) Manufacturer Strength: 5. If you do NOT want your identity disclosed User Fecility Manufacturer: to the manufacturer, place an "X" In this box:

FORM FDA 3500 (1/09)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

The patient has a history of severe pouchitis characterized by abdominal cramping, diarrhea and dehydration. Her longest remission has been 3 weeks. She has recurrent bouts of pouchitis which she ends up in the Emergency Department for hydration and antibiotics. I received information on January 19, 2015 from her physician that she began having a flair and would go on vancomycin. After a few days she felt better, but she usually relapses at 5 days. She went off her antibiotics on January 24. She had a fecal transplant on (b) (6), (b) (4) on January 27, 2015. She noted having continued cramping and diarrhea as before, but the cramps were more intense. A few days later she went to Emergency Department and she was admitted for antibiotics and IV fluids. She was in the hospital 36 hours and is doing better now.

Individual Case Safety Report

10788078-01-00-02

DSS RÉB 1 1 191 ulcerative colitis total proctocolectomy with ${\cal C}$ pouch ileganal anastomoxis

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Individual Case Safety Report

10788078-01-00-03

DSS B11200 One fecal transplant on January 27, 2015

Individual Case Safety Report

10788078-01-00-04

DSS FEB 1 1 2003

CBER

10904669-01-00-01 Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse. U.S. Department of Health and Human Services For VOLUNTARY reporting of MEDWATCH adverse events, product problems and product use errors The FDA Safety Information and Adverse Event Reporting Program Page 1 of 0 Frequency Route A PATIENT INFORMATION 1660 Female Male Dates of Use (if unknown, give duration) from to for best artimate! 5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Apply 2/27/2015 Product Problem (e.g., delects/mailunctions) Product Use Error Problem with Different Manufacturer of Same Medicine #2 Yes No Doesn't 2. Outcomes Attributed to Adverse Event 4. Diagnosis or Reason for Use (Indication) 8. Event Reappeared After Reintreduction? (b) (6) #1 Yes No Doser Deeth: Disability or Permanent Damage Congenital Anomaly/Birth Defect Life-threatening #Z Yes No Dossn' Apply 7. Expiration Date Hospitulization - initial or prolonged () Other Serious (Important Medical Events) #1 B. NIDC # or Unique ID Required Intervention to Prevent Permanent Impairment/Damage (Devices) 82 4. Date of this Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yyyy) F SUSPECT MEDICAL DEVICE 0310112015 C 03/03/2015 1. Brand Name Denta acrona < dolp 2. Common Device Name CTU infection in an imment -3. Manufacturar Name, City and State compromised probable who MAR - 9 20 5 and not respond to copy 5. Operator of Davice 4. Model # Late Heelth Professional Pr, received FINT Expiration Date (mm/t/d/yyyy) Lay User/Patient Catalog # Other: Unique Identifier (UDI) # Serial # C LIN 00 2/15/2015 (pre) 7. If Explanted, Give Date (mm/dd/yyyy) 6. If implented, Give Date (mm/dd/yyyy) 3(1)2015(加來) 8. is this a Single-use Device that was Reprocessed and Reused on a Pallem? Yes No 9. If You to Item No. S. Enter Name and Address of Reprocussor Other Relevant History, including Preatisting Medical Conditions (e.g., allergies, race, pregnancy, smolding and alcohol use, liveritidney problems, etc.) F. OTHER (CONCOMITANT) MEDICAL PRODUCTS as and therapy dates (exclude treatment of event)

G. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

(mm/dd/yyyy)

Yes No Returned to Manufacturer on:

SUSPECT PRODUCT(S)

eme, Strength, Misnufacturer (from product label)

5400) ama:

Strength: Monufacturer: OPSEN BIOME

#2 Name:

Strength: Manufacturer:

FORM FDA 3500 (2/13)

Distributor/Impor to the manufacturer, place an "X" in this box: Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Yes No

7 Health Professional? 3 Decupation

6. If you do NOT want your identity disclosed

G. REPORTER (See confidentially section on back)

1000

DSS

Manufacturer

User Facility



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program (CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

8.5. Describe Event or Problem (continued) 81 yo men I soute drawbe in the setting of vacuation tracted VI situan Pradmusing C. doll &, who did not report to variangin po 2- by evens & IV metroridogiste diacensed Frat by colonomy (which about around passed or marchenes withis) empresed wietly, north res & start Lidely, then become atmostly, somety it, mother hypotic decidoris, decided.

B.6. Relevant Tests/Laboratory Date, Including Dates (continued)

2/15/2015 area c. ch/19 comp atrain: 3/1/2015 " " C & O27/NAPI BI

Day of drath gluces 33, loves 3.6, and x-ray neg for perforation

8.7. Other Relevant History, including Preexisting Medical Conditions (e.g., ellergies, race, prepnancy, smoking and alcohol use, hepatichenal dysfunction, etc.) (continued)

Renal barbera formania proposion 0m2

F. Concomitant Medical Products and Thorapy Dates (Exclude treatment of event) (continued)

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RY reporting of fuct problems and CBER

Form Approved: CMB No. 0910-0291, Expires: 8/30/2015 See PRA statement on reverse.

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Advance Evout Reporting Program	Page	1013	6	0553	52
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(b) (6) (b) (6)	4. 5000504	#1 250mL stop	1 Once	Color	овсору
(b) (6) Female	162.8 lb	102			
in confessore	ar 74 tag	"			
E ACVERSE EVENT PRODUCT PROBLEM OR ER		3. Dottes of Ven (II un	lunown, give duration)		nt Abelted After Use
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L. Alivenne Bresst Preduct Predition (e.g., delectarmellinat		#1 03/30/2015			Yes No Do
Product the Serer Problem with Officent themsecturer of	7 Dame Medicine		- Read has dedicated	#2	Yes No Dos
Outcomes Attributed to Adverse Brent (Check of that apply)		4. Diagnosis or Rose #1 Severe recu	rrent C. diffi		nt Recomposered After
Desith: Dissibility or Permanent I	Dumage	infection		Reta	troduction?
(mm/dd/yyyy) [] Life-threetening [] Congenite! Anomely/Bett	h Distinct	#2		#	Yas □ No ☑ Dos
☐ Hospitalization - initial or protonged ☐ Other Serious (Important		6 (2)	7. Expiration E	Metho #2	Yes No Dos
Required latervestion to Prevent Permanent Impelsesent/Demage		(b) (6)	#1 09/24/	2015	App (ID)
3. Date of livent (mm/0d/yyyy) 4. Date of this Report (m	um/dislAvinn/)	#2	#2	(b)	(6)
04/13/2015 D6/30/2015	,,,,,,	E Suspecime	EDICAL DEVICE		
5. Departies Event, Problem or Product Use Sever		1. Drand Numo			
86 y/o man with PMHx of Klebsiella pneumonia tract infection (10/2014), ESRD on HD (since	urinary	N/A			
DM, CAD s/p CABG, CHF (EF 45%), HTW with rec	urrent,	2. Common Davice M	cento	2b	Precede
severe, refractory C. difficile infection for antibiotic treatment for others media (9/201					
10/2014, 1/2015) who had a Fecal Microbiota :	Transplant	3. Manufacturer Name	City and Bhate		
perfor (b) $(6)^3/30/15$ with donor stool from 0 (Item (b) (6) unit ID (b) (6) exp 9/24/15	pen Biome		y any and call		
was doing well initially after transplant wit	th dally				
formed bowel movement, which was documented a note on 4/2/15. Approximately 1 week after FI		4. Model #	Let®		5. Operator of Dovi
patient developed hematuria and was referred					Health Professio
Emergency Room.		Catalog (I	Sentrolen D	min (montale)	Lay User/Patient
				- printe de yyyy,	
. Rolovent Teste/Lebrontory Date, including Dates		Soriel 0	Unique Idea		Diher:
Stool Culture 4/13/15: Salmonelia Group Cl		eta sur o	Others result	mist (ons) o	
Blood Culture 4/13/14: No growth after 5 days C. difficile 4/13/15, 1/9/15, 10/14/14, 9/12/					l
Detected by PCR for Toxin B Gene or EIA for C difficile toxin A/B	c.	8. If Implanted, Cive D	ese (mm/ad/yyy)	7. W Explanded, C	itvo Dato (mm/did/yyy)
Stool Culture 1/9/15 and 1/15/15: No Salmonel	lla,	8. Is this a Single-use	Dovice that was Nep	recessed and Re	wood on a Pationt?
Shigella, Campylobacter or Yersinia Isolated		Yes No			
		9. If Yes to flom No. 0, 5	inter theme and Adena	ss of Reprocessor	
. Other Relevant Michery, Inchesing Presidenting Medical Conditions allergies, race, pregnancy, emoling and closhel use, inverhidney prob	10.g.,				
1. Severe, recurrent CDI following antibiotic		E ATUED ICANIC	COMITANT) MED	JENI BINGSI	Name of the last o
treatment for otitis media (9/2014, 10/2014, 2. End-Stage Renal Disease on hemodialysis (s	1/2015).	Product names and th			
8/2014)					•
3. Type 2 DM 4. Coronary heart disease (previous CABG)					
5. Congestive heart failure (EF 45%)					
6. Hypertension		G REPORTER 15	ce confidentality	section on b	
PRODUCT AVAILABILITY				11	
reduct Available for European (Do not send product to FDA)					
Yes No Returned to Manufacturer on:	MATERIA			16	
SUSPECT PRODUCTION	w yyyy)				
Merro, Strongth, Clarafecturer from product lebel)				16	
Name: Donor Stool (Item #: (b) (6) Unit ID: (b	0) (6)				
Strongth: 250mL Menufacturer. Open Biome		2. Health Professional	7 3 Demmetter		Alex Box and the
Name;		Yes No	Physician	4	Also Reported to:
a work a way			1 relearning		MINISTER STATES

Strength:

5. If you do 1997 can't your identity disclosed to the menufacturer, place on "R" in this ben:

User Facility
Distributor/Importer



THE THE CHEST ENGINEERS AND Adverse Event Reporting Program

IARY reporting of and product problems

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He was admitted to (b)(6) on (b)(6) days s/p FMT) with sepsis from emphysematous cystitis (urine culture: Klebsiella pneumoniae ssp pneumoniae. Patient was initially treated with ceftriaxone 1g IV daily and had persistently formed bowel movements until treatment with antibiotics. He then developed loose stools secondary to recurrent C. difficile and Salmonella Group C1 without bacteremia. He was treated with a prolonged course of trimethoprim-methoxazole and cephalexin as well as vancomycin 500mg PO q6.

Two months after hospitalization, the patient was evaluated in GI clinic. He completed his antibiotics including vancomycin without any clinical signs of infection. He has formed daily bowel movements without abdominal pain. He had no identifiable risk factors for salmonella infection.

B.B. Relovant Tests/Laboratory Date, Including Dates (continued)

Urine Culture 4/9/15: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae Urine Culture 10/24/14: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae

CT A/P (b) (6) IMPRESSION: 1. Thickwalled urinary bladder with surrounding inflammatory change. Foci of gas are present within the bladder lumen, and along the bladder wall. While some of the mural foci may be within diverticula, others appear to be intramural. Additionally, two small foci of gas are noted adjacent to the bladder, but completely external to it. At least one of these foci appears to be venous (image 46 of the coronal series), and the other likely also is as well (image 78 series 3). No free fluid around the bladder to suggest frank bladder perforation. Overall findings are consistent with emphysematous cystitis. This was reported to (b) (b) at 7:34 a.m. on (b) (b) 2. Adjacent sigmoid colon is unremarkable, without evidence of inflammation. 3. Bilateral pleural effusions. 4. Nodular liver contour suggestive of parenchymal disease. 5. Abnormal lymph node anterior to the right hip, just lateral to the sartorius muscle, measuring 17 mm, nonspecific. This may be reactive, a metastatic node cannot be excluded.

B.7. Other Relevant Michary, Including Presideting Medical Conditions (e.g., allergies, rece, pregnancy, amoking and alcohol use, hepaticirenal dystunction, etc.) (continued)

7. Klebsiella pneumoniae urinary tract infection

F. Concomitment Modical Products and Thomasy Dates (Exclude treatment of event) (continued)

DSS JUL 16 201

(b) (6)

Ph. Ph. A. A	ARY reporting of product problems and	Š	OMD No. 0910-0201, Engines: 8/30/20 See PRA Statement on reven
Advance Event Connector .	duct use errors	Triago unit sequenço d	
A PATIENT INFORMATION 1. PERIOR ISONATOR 2. Ago at 1500 of Event or 3. See 4. See 4. See	Page 1 of 3	60	8168
(D) (6) Good of Blem:	to 81 250 ml	Proquency	Feeding Febr
in confidence (D) (O) PROGUET PROGLEM OR ERROR	_ '		
Chest all that apply; 1. Placerto Event Preduct Predicts (e.g., coloratificiunations) Product Use Error Predicts with Different Monerfacturer of Same Man	In Marian	ern, give duration) fremno	S. Event Abelted After Use Stepped at Dece Reduced? E1 Yes No Posset
Outcomes Agributed to Adverse Event (Grack at that apply)	4. Disgassis er Ressen	For Use (Indication)	#2 Yes No Dosen's
Disability or Permunent Demago [Title-threatening	Re world	CA.F.	8. Event Reeppoered After Reintrespetion? 101 Yes No Possen't
The particular of initial or prolenged Cother Serieus (Important Medical Ev Required Intervention to Prevent Permanent Impeliment/Damage (Produce)	(b) (6)	7. Empirellon Data	82 Yes No Desert
4. Date of this Report Immissional		82 8-4-2015	B. NDC & or Unique ID
5. Describe Event, Problem or Product Use Error	E SUSPECT MEDI	CAL DEVICE	
Pt with No recurrent c. diff presented to Er with 5 day Wo dien has/blood is stool.	2. Commen Davico Hama		CTU
& Luned Openhame Stol Transplant 6/25/15.	2 Marie		JUL 31 201
if the whereapy (1) (1) should endunite internal)	y and State	
places of deep vicention.	4. Model if	Let	6. Operator of Davice
	Cathley 6		Month Professional
6. Relovent Testad absentery Dete, Including Dates	Causing	Expiration Date (mm)	Lay User/Patient
CT and -> intlammation in the according of	Bortol S	Unique Montiller (UDI	Other:
of altis	6. W Implement, Give Date (fi	nm/dd/yym 7. W Explo	nkod, Give Date (mm/od/yyyy)
Broken a few for about for any shore a few	8. in this a Single-use Devic	o that was Represented	and Roused on a Patient?
7. Other Relevant Matery, including Prentitating Medical Conditions (e.g., storages, rets, preprinty, smooting and alcohol use, invertiging problems, etc.) Culff 1915 1 206 207 207 207 207 207 207 207	3 1/4		
	The standard of the control of the c	TANTI MEDICAL PR	ODUCTS
72 CAP 181.5	Product names and thorapy	estes (estica estes) surce	Vercall
PROPERTY	G REPORTER Sen ga	alizantally vertical	do Agent
C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)	1. Name and Address Name:	<i>y</i>	0.0
Yes No Returned to Manufecturer on:	Address:		DSS JUL 81 20
1. Nome, St. (b) (6) for from product table (b) (6)	City:	Sizio:	ZIP: JUL 81 20
Grangen;	2 Marillo D. C.		
Strongs:	2. Month Profosolonal? 3. Co		4. Alne Reperied to:
Monufacturer: FORM FDA \$500 (2/13) Submission of a report store by consultant and	5. If you do MOT want your Mont to the menufacturer, place an	It's in this bex:	User Facility Distributor/imperier



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adverse events and product problems

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IVICUVVAICH
The FDA Sefety information and
Adverse Event Reporting Program

hadsinted (b) (6) with recurrent bloody disober and arenois. (b) (6) garaceloris treatment in addition to receiving PRBC transvision (3 onits), bloo desidency a apen I week garaceloris with and valganceloris for flo h... on (b) (6), he was rendmitted with expsis like syndrome. Blood authors were positive for E. odi. CT of abdome are reducing impressive. Ultrasound of gelleballs (b) (6) with reducid distriction 3 stones, wall theretroising or perichologythe Phid whether. Ultrasound to perforation to or free lapportrasy and probable whethery. Postop he: following this, descending who perforation and introducing appears. Paths wall suggests: "late sagnals of the underlying direct process. No specific feature are identified to suggest a cause for the ulcerations."

Be. Roborent Yesterletermenty Doro, Including Doros fearthurson

Stock regative for completerity, a diff tomin 4B, Pleasonmen Shighlaides, Salmonelly appropriate for completerity, a different plans, cutero against the E. edi,

Litero patho genic. E. edi, a teo tox; genic E edi, Shiga. liter Toxind producing E. edi,

Shighla/Enters invasive E. edi, engo to sporidium, cy clospone cayo tamensis, Enterenter,

his To lytica, Giardia lamblia, add novirus F salvi, ashovirus, avorvina GZ/Cai, rotovina A

E. Sopo virus.

B.T. Other Relevant Metary, Including Pressioting Challes Considers (a.g., adergies, race, pregnancy, smoking and electrol use, happelichanal dysfunction, etc.) (continued)

F. Concomitant Modical Products and Thompsy Dates (Enclude transment of event) (continued)

DSS JUL 31 2015

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse.

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ase errors
Page 1 of Z

FDA USE ONLY					
Triage unit sequence #					
1014108					

o godiene	WEODINATION			2. T	Pase of Am	nount	Freque	nev 1	Route		
A. PAULENU	INFORMATION 2. Age at Time of Event or Date of Birth:	13. Sex	4. Weight		250 cc	nount	- Treque			doscopy	
b) (6)											
	87	✓ Female	lb	#2	250 cc		$\neg \vdash \vdash$	——i	sigmoi	doscopy	
in confidence		☐ Male	or kg						,		
	EVENT, PRODUCT PR	OBLEM OR ER	ROR	3. Dat	es of Use	(II unknown	, give duration	n) from/to		t Abated Afte	
check all that appl	the second secon			1	best estima					d or Dose Re	
I. Adverse Ev	ent Product Problem (e	.g., defects/malfuncti	ions)	· I —	/02/201				#1 LJY	res No	Apply
Product Use	Error Problem with Differ	ent Manufacturer of	Same Medicine	1	/23/201				#2 🗍	res No	Doesn
2. Outcomes Attr	ibuted to Adverse Event				_		Use (Indicati			t Reappeare	Apply
(Check all	(b) (6)					recurre cile inf	nt & refr ection		Reint	roduction?	
Death:	(mm/dd/yyyy)	bility or Permanent E	Jamage	_		nt C dif			#1 🔲 ነ	res No	Doesn Apply
Life-threaten		genital Anomaly/Birth	n Defect		nfection	on			#2 🗔	res No	✓ Doesn
	on - initial or prolonged 🔲 Other			6. Lot		`	7. Expiration	n Date			VPbli
Required Int	ervention to Prevent Permanent	Impairment/Damage	(Devices)	<u> *</u> "(o) (6))			9, NDC	# or Unique	ID
3. Date of Event	(mm/dd/yyyy) 4. Da	te of this Report (m	m/dd/yyyy)	#2			#2				
08/01/201	5 08,	/24/2015		A DESCRIPTION OF		TMEDIC	AL DEVIC	E			
	t, Problem or Product Use Erro			1. Bra	nd Name						
87 y/o F a	dmitted with severe, (CDI) which did not r	complicated C	difficile eeks of								
standard m	edical therapy (IV me	tronidazole/P	O vanco.	2. Co	nmon Dev	rice Mame			2b.	Procode	
	er 3rd C diff episode								p.	18	
	with some improvement n afterwards for risi			2 100	fa abusas	Name, City	and Clata		7		
diarrhea.	She was discharged to	a rehab faci	lity for	3. 1918	nuracturer	name, City	and State	0.1	ED 3	a 2016	
	sues of weakness, deb line. FMT repeated a							\$1	cr 1	0 2015	
sigmoidcsc	opy on 07/23/15 (Open	biome (b) (6)		1 00-	4-4-4		Lot#			5. Operator	of Davie
procedure	uncomplicated. Vanco	was held. She	declined	4. Mo	D-01 #F		LUI W			1	
	with confusion, pain gh to indicate), cont							Health Profession			
10010 01100	3			Cat	alog#		Expiratio	n Date (mm	/dd/yyyy)	Lay Use	r/Patient
										Other:	
6. Relevant Tests	/Laboratory Data, Including D	ates		Sei	iel#		Unique la	ientifier (UE	OI) #	-	
none								•			
							411/4	I m to m			
		•	1	6. H lir	nplanted, (Give Date (mm/dd/yyyy)	7. If Exp	ianted, G	ilve Date (mi	noayyyy)
			· ·	8. ls t	his a Singl	le-use Devi	ce that was F	Reprocesse	d and Re	used on a P	atient?
			1		Yes N	40					
				9. HY	es to item ?	No. 5, Enter	bA bre eme	iress of Rep	rocessor	7	
7 Other Selevani	: Illatory, Including Preexisting	Medical Condition	B (e c								
allergies, reca, j	pregnancy, smoking and alcohol	usa, liver/kidney pro	blems, etc.)								
	congestive heart fail n), delerium, anxiety			Annual Contraction	-		IITANT) M				4
	lemia, h/o breast cand		•				y dates (excli				
			:				ril, clona n, mirtaza				profen
			ì				•	•			•
				6 6	GOODE	(a) (900)	var (Belleva (Be	Mary analy	YOU CATE ON	code	2
				(c) (r		-W (1926) (onfidentia	पार्थ श्रवस्ता	M ON D	CIA'S	i
C PRODUCT	AVAILABILITY									20	
Product Available	for Evaluation? (Do not send	product to FDA)									A
Yes No	Returned to Manufecture	er on:	i								
D. SUSPECT	PPARIETIE	(mm/c	od/yyyy)		-						
The Contract of the Contract o	n, Manufacturer (from product)	nhel)		1					0		
1 Name: Donor	Stool (Openbiome (t) (6) -used 7	7/23/15	3				1			
Streng'n:		, in m 1891				ما مدر از	0			Also Borre	and do:
Manuf acturer:	Openbiome			и _			Occupation		4	. Also Repor	
	stool (Openbiome (b) (6) -used	7/2/15		Yes 1		ysician			✓ Manufac	
Strength:							ientity disclor an "X" in this			Distribut	-
Man ifacturer:	Openbiome			10.1	ne manurai	curer, piace	ALL V. ILI MIR	20X.		Cistinal	

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Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the even

(b) (6)

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ARY reporting of ad product problems

The FDA Safety Information and Adverse Event Reporting Program

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B.5. Describe Event or Problem (continued)	
abdominal distension. She	did not undergo any diagnostic evaluation for this decline. The family
decided to pursue hospice,	where she died or $(b)(6)$ days post second FMT).
B.6. Relevant Tasts/Laboratory Data, Include	sing Dates (continued)
•	
	1
B.7. Other Relevant History, Including Pres	xisting Madical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
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	i'
_	
F. Concomitant Medical Products and Ther	apy Dates (Exclude treatment of event) (continued)
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